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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,314	12/20/2001	Carlos Forray	1795/57453-CA/JPW/ADM/PL	4321

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EXAMINER	
CRIARES, THEODORE J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/029,314	FORRAY ET AL.	
	Examiner	Art Unit	
	Theodore J. Criares	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *169-197* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *169-197* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/22/02 &2/05/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

CLAIMS 169-197 ARE PRESENTED FOR EXAMINATION

DETAILED ACTION

Applicant's arguments filed February 12, 2004 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicants are advised that upon filing an answer to this Office Action Claim 168 should be included in the canceled claims.

Applicants argue that:

1. the claimed invention is a method of treating an eating disorder or obesity in a subject which comprises administering to the subject a therapeutically effective amount of an MCH1 antagonist or an MCH1 agonist wherein each agent would inhibit the activation on NPY1 receptor to a desired degree to treat the eating disorder or obesity depending on the strength of the agent. It is applicants' position that it is irrelevant whether one skilled in the art could make any specific compound or all such compounds without undue experimentation.

The applicants were not in possession of all the multitude of compounds which would meet the criteria set forth in the specification asof the date of filing of the subject application. In view of the Applicants' argument it is deemed that the rejection under 35 USC 112, first paragraph is proper.

Claims 169-197 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds as set forth of by the compounds exemplified, does not reasonably provide enablement for the biological method of treatment as claimed in claims 169-197. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims encompass an astronomical number of compounds which have a specific inhibition of a biological pathway without setting forth the compounds exemplified in the specification. The skilled artisan would not be able to determine which compounds are within the scope of applicants' claims without undue experimentation.

Claims 169-197 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compounds set forth in the specification does not reasonably provide enablement for compounds which require undue experimentation to determine there activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. In addition to the above after determining the compounds to be used in the practice of the invention the activity of the compounds has to be determined. The essential compounds taught by the specification are within the scope of applicants' invention and are enabled.

In view of the above contrary to the applicants' allegation that it is irrelevant whether one skilled in the art could make any specific compound or all such compounds without undue experimentation it is the examiner's position that it is extremely relevant

since the applicants did not have all of the compounds that would have the effect of treating anorexia nervosa in their possession.

2 Bruce fails to teach all of the elements of applicants' claims as required by 35 USC 102(a). However, the Examiner's position is that the compounds taught at column 11, lines 1-20 in Bruce when administered to a patient would treat an eating disorder as taught by the reference at column 12 lines 53-65. The inhibition of the biological pathway would be inherent. There has been no evidence proffered by the applicants to overcome this rejection. The burden is on the applicants to establish that these compounds would not have the effect on the NYP1 receptor as claimed by applicants. Bruce teaches in the citation that the compounds reduce food intake and function as an anti-obesity agent.

Therefore, the rejection under 35 USC 102(a) is deemed proper since the claims are drawn to a mechanism of action which are effective to treat anorexia nervosa.

The rejection under 35 USC 102(a) is maintained as follows:

Claims 169-197 are rejected under 35 U.S.C. 102(a) as being anticipated by Bruce et al.(5,889,016, hereinafter referred to as Bruce).

Bruce teaches in the abstract (Formula I) and at column 4, line 66 to column 12, line 45 dihydropyrimidinone compounds can be administered to treat eating disorders. At column 12, lines 34-35 it is taught that dihydropyrimidinone compounds have utility in the treatment of "food intake disorders, such as obesity, anorexia, bulimia, and metabolic disorders;".

The biological pathway as claimed by the applicant in claims 167-197 would be inherent in the administration of the compounds taught by Bruce to treat eating disorders.

3. the instant claims are not obvious over Bruce under 35 USC 103(a) since the reference does not have any teachings or suggestions that one can make changes or modifications to Bruce's exemplified structure and still maintain an effective treatment.

However, one of ordinary skill in the art would have been motivated to use the compounds taught therein, which are taught to treat eating disorders, since the basic moieties are similar.

Therefore, claims 169-197 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruce et al., (supra).

As stated above Bruce teaches the administration of a dihydropyrimidinone can treat eating disorders including the treatment of eating disorders and obesity, claims 169-191 and eating disorder of claims 192-197.

The difference between the applicants' claims and Bruce is that the dihydropyrimidinone compounds differ as the phenyl moiety is substituted with the piperizine moiety. However, the skilled artisan would be motivated to use the Bruce compounds with a reasonable expectation of success since the reference compounds are so similar to those disclosed in the specification that they would be expected to treat the claimed eating disorders.

That applicant may have determined a biological pathway by which the active ingredient gives the pharmacological effect does not alter the fact that obviously

similar compounds have been previously used to obtain the same pharmacological effects which would result from the claimed method. The patient, condition to be treated and the effect are the same. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompassed by the claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 167-196 are rejected under the judicially created doctrine of double patenting over claims1-18 of U. S. Patent No. 6,720,324 since the claims, if allowed, would improperly extend the **"right to exclude"** already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: the claims in the application are drawn to the inhibition of a biological pathway. The compounds of claims 1-18 of 6,720,324 are the same compounds taught at pages 250-259 and 346-358 of the specification to inhibit the biological pathway to treat eating disorders. It would be obvious to use the compounds taught by the patent to treat eating disorders. It is recognized by the examiner that the disorder of claim 197 is not taught by the reference. The method claimed in the present application could have been claimed in the patent. This obvious type double Patenting rejection is deemed proper.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Applicant is advised to review their Patent portfolio to determine if additional Obvious Double Patenting situations are possible that relate to the subject application.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is (571) 272-0625. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Theodore J. Criares
Primary Examiner
Art Unit 1617

4/5/04
tjc